Louisiana Medicaid
Growth Hormones

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for growth hormone agents.

Additional Point-of-Sale edits may apply.

*These agents may have **Black Box Warnings** and/or are subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety Regulations. Please refer to individual prescribing information for details.*

ADULTS AND CHILDREN		
Somatropin Brand Examples	**Required ICD-10 Codes**	**Diagnosis Description**
Genotropin®, Humatrope®, Norditropin®, Nutropin AQ®, Omnitrope®, Saizen®, Zomacton®	**E23.0** **E23.1** **E89.3**	Growth Hormone Deficiency (GHD) - Adult, Children o Iatrogenic Hypopituitarism o Drug-induced Hypopituitarism o Post Procedural Hypopituitarism
Nutropin AQ®	**N25.0**	Growth failure in children associated with renal insufficiency or chronic kidney disease; until the time of renal transplantation
Genotropin®, Humatrope®, Norditropin®, Nutropin AQ®, Omnitrope®, Zomacton®	**Q96***	Turner Syndrome
Genotropin®, Norditropin®, Omnitrope®	**Q87.1**	Prader-Willi Syndrome
Norditropin®	**Q87.1**	Noonan Syndrome
Genotropin®, Humatrope®, Norditropin®, Omnitrope®, Zomacton®	**P05.1***	Small for gestational age at birth (fetal growth retardation) who fail to manifest catch-up growth or with no catch-up growth by age 2 to 4.
Humatrope®, Zomacton®	**E34.3**	Short stature or growth failure in short stature homeobox-containing gene (SHOX) deficiency
ADULTS ONLY		
Serostim®	**R64**	HIV-associated cachexia or wasting
Zorbtive®	**K91.2**	Post-Surgical Malabsorption NEC (Alternative name: Short Bowel Syndrome)

*Any number or letter or combination of **UP TO FOUR** numbers and letters of an assigned ICD-10-CM diagnosis code

Approval Criteria

- The recipient has an appropriate diagnosis for the agent requested (see table above); **AND**
- The growth hormone is prescribed by, or the request states that the medication is prescribed in consultation with, an endocrinologist, gastroenterologist or nephrologist (as applicable); **AND**
- Previous use of a preferred product – **ONE** of the following is required:
    - The recipient has had a *treatment failure* with an adequate trial (3 months) of at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* with at least one preferred product; **OR**
    - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate to use for the condition being treated; **OR**
    - There is *no preferred product appropriate* to use for the condition being treated; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling; **AND**
    - There is confirmation of open growth plates in recipients older than 12 years of age (if applicable).

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of initial and reauthorization approval:

- For post-surgical malabsorption: **4 weeks**
- For HIV-associated cachexia or wasting: **12 weeks**
- For all other diagnoses (NOT post-surgical malabsorption or HIV-associated cachexia or wasting): **12 months**

References

Genotropin (somatropin) [package insert]. New York, NY: Pfizer Inc; April 2019. http://labeling.pfizer.com/ShowLabeling.aspx?id=577

Humatrope (somatropin) [package insert]. Indianapolis, IN: Eli Lilly and Company; October 2019. http://pi.lilly.com/us/humatrope-pi.pdf

Norditropin (somatropin) [package insert]. Plainsboro, NJ: Novo Nordisk Inc; March 2020. https://www.novo-pi.com/norditropin.pdf

Nutropin AQ (somatropin) [package insert]. South San Francisco, CA: Genentech Inc; December 2016. https://www.gene.com/download/pdf/nutropin_aq_prescribing.pdf

Omnitrope (somatropin) [package insert]. Princeton, NJ: Sandoz Inc; June 2019. https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=58d84ffa-4056-4e36-ad67-7bd4aef444a5&type=display

Saizen (somatropin) [package insert]. Rockland, MA: EMD Serono Inc; February 2020. https://www.emdserono.com/us-en/pi/saizen-ce-pi.pdf

Serostim (somatropin) [package insert]. Rockland, MA: EMD Serono Inc; June 2019. https://www.emdserono.com/us-en/pi/serostim-pi.pdf

Zomacton (somatropin) [package insert]. Parsippany, NJ: Ferring Pharmaceuticals; July 2018. http://www.ferringusa.com/wp-content/uploads/2018/07/ZOMACTON-PI-7-18.pdf

Zorbtive (somatropin) [package insert]. Rockland, MA: EMD Serono Inc; September 2019. https://medical.emdserono.com/content/dam/web/health-care/biopharma/web/USMI/Forms/Zorbtive_PI.pdf

Revision / Date	**Implementation Date**
Single PDL Implementation	May 2019
Removed Fee-for-Service from title, made formatting revisions, removed footer / December 2019	January 2020
Updated SHOX diagnosis code, updated indications, formatting changes, updated references / May 2021	October 2021